

06-26-06

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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JFW



# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

|   |  |                        |                            |
|---|--|------------------------|----------------------------|
| <b>TRANSMITTAL FORM</b><br>(to be used for all correspondence after initial filing) |  | Application Number     | 10/748,999                 |
|   |  | Filing Date            | December 29, 2003          |
|   |  | First Named Inventor   | Rozalina Dimitrova         |
|   |  | Art Unit               | 3767                       |
|   |  | Examiner Name          | Benjamin Huh               |
| Total Number of Pages in This Submission  |  | Attorney Docket Number | ALLE0063-100 (17638 (BOT)) |

## ENCLOSURES (check all that apply)

|  |  |   |
|--|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input checked="" type="checkbox"/> Fee Attached/Authorized<br><input type="checkbox"/> Amendment / Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Supplemental Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Reply to Missing Parts/Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):<br>Forms PTO SB/08a and SB/08b (2 pp.); (11) References Cited, (7) References Enclosed. |
| <b>Remarks</b><br>EXPRESS MAIL LABEL NO: EV147618876US<br>DATE OF DEPOSIT: 6/22/06<br>EV147618876US  |  |   |

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|              |                           |          |        |
|--------------|---------------------------|----------|--------|
| Firm         | Cozen O'Connor            |          |        |
| Signature    |                           |          |        |
| Printed Name | Daniel M. Scolnick, Ph.D. |          |        |
| Date         | 6/22/06                   | Reg. No. | 52,201 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

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| Signature             |  |      |  |
| Typed or printed name |  | Date |  |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL for FY 2006

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 180.00)

## Complete if Known

|                      |                            |
|----------------------|----------------------------|
| Application Number   | 10/748,999                 |
| Filing Date          | December 29, 2003          |
| First Named Inventor | Rozalina Dimitrova         |
| Examiner Name        | Benjamin Huh               |
| Art Unit             | 3767                       |
| Attorney Docket No.  | ALLE0063-100 (17638 (BOT)) |

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☒ Other (please identify) : Deposit Account☒ Deposit Account Deposit Account Number: 50-1275 Deposit Account Name: Cozen O'Connor

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s)☒ Credit any overpayments

Under 37 CFR 1.16 and 1.17

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

## FEE CALCULATION

## 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

| Application Type | FILING FEES |                      | SEARCH FEES |                      | EXAMINATION FEES |                      | Fees Paid (\$) |
|------------------|-------------|----------------------|-------------|----------------------|------------------|----------------------|----------------|
|                  | Fee (\$)    | Small Entity Fee(\$) | Fee(\$)     | Small Entity Fee(\$) | Fee(\$)          | Small Entity Fee(\$) |                |
| Utility          | 300         | 150                  | 500         | 250                  | 200              | 100                  | _____          |
| Design           | 200         | 100                  | 100         | 50                   | 130              | 65                   | _____          |
| Plant            | 200         | 100                  | 300         | 150                  | 160              | 80                   | _____          |
| Reissue          | 300         | 150                  | 500         | 250                  | 600              | 300                  | _____          |
| Provisional      | 200         | 100                  | 0           | 0                    | 0                | 0                    | _____          |

## 2. EXCESS CLAIM FEES

## Fee Description

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

| Fee (\$) | Small Entity Fee (\$) |
|----------|-----------------------|
| 50       | 25                    |
| 200      | 100                   |
| 360      | 180                   |

Total Claims Extra Claims Fee(\$)

\_\_\_\_\_ -20 or HP= \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims Extra Claims Fee(\$)

\_\_\_\_\_ - 3 or HP= \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee (\$)

## 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof                | Fee (\$) | Fee Paid (\$) |
|--------------|--------------|---|----------|---------------|
| _____        | _____        | _____ / 50 = _____ (round up to a whole number) x _____ = _____ | _____    | _____         |

## 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Information Disclosure Statement

Fees Paid (\$)

\$180.00

## SUBMITTED BY

Signature

Registration No.  
(Attorney/Agent)

52,201

Telephone

415 665 6728

Name (Print/Type)

Daniel M. Scolnick, Ph.D.

Date

6/22/06

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **Dimitrova, Vandenburg and Walcott**

Serial No.: 10/748,999

Group Art Unit: 3767

Filing Date: **December 19, 2003**Examiner: **Benjamin Huh**For: **Botulinum Toxin Injection Guide**EXPRESS MAIL LABEL NO: EV147618876US  
DATE OF DEPOSIT: 6/22/06

**Mail Stop Amendment**  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Forms SB/08A and SB/08B, formerly known as PTO Form 1449, submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Supplemental Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☐ **before** the mailing date of a first Office Action on the merits.
- ☐ **before** the mailing date of a first Office Action on the merits after the filing of

Request for Continued Examination under § 1.114.

06/27/2006 MAILED1 00000109 501278 10148799  
01 FC:1806 180.00 DA06/27/2006 MAILED1 00000109 10748999  
01 FC:1806 180.00 DA

- ☒ **after** the mailing date of a first Office Action on the merits or after the filing of a Request for Continued Examination under § 1.114, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or
- ☒ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with the ☐ first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), and the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p).
- ☒ Copies of the references (except the U.S. Patent Documents) listed on the attached PTO Forms SB/08A and SB/08B, formerly known as PTO Form 1449, are enclosed.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of references, and the likelihood that these reference are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) @@ for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 C.F.R. § 1.704(d)**

- ☐ The undersigned attorney hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and the communication was not received by any individual designated in §1.56(c) more than 30 days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☐ No Fee is owed by the applicant(s).
- ☒ The Supplemental Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☒ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☐ No fee or Statement is required under 37 C.F.R. § 1.97(b).

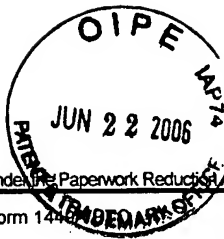
Dated: *6/22/06*

COZEN O'CONNOR, P.C.  
1900 Market Street, 5<sup>th</sup> Floor  
Philadelphia, PA 19103-3508  
(215) 665-2000 – Telephone  
(215) 665-2013 - Facsimile

Respectfully submitted,



**Daniel M. Scolnick, Ph.D.**  
Registration No. 52,201



PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

|                        |                            |
|------------------------|----------------------------|
| Application Number     | 10/748,999                 |
| Filing Date            | December 29, 2003          |
| First Named Inventor   | Rozalina Dimitrova         |
| Art Unit               | 3767                       |
| Examiner Name          | Benjamin Huh               |
| Attorney Docket Number | ALLE0063-100 (17638 (BOT)) |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Document Number                            | Publication/Issue Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|------------------------|--------------------------|--|--------------------------------------|--|---|
|                        |                          | Number - Kind Code <sup>2</sup> (if known) |                                      |  |   |
|                        | AA                       | US-3,547,121                               | 12-15-1970                           | Cherry   |   |
|                        | AB                       | US-3,999,504                               | 12-28-1976                           | Gardiner   |   |
|                        | AC                       | US-4,362,157                               | 12-07-1982                           | Keeth  |   |
|                        | AD                       | US-2002/0086036                            | 07-04-2002                           | Walker   |   |
|                        |                          | US-  |                                      |  |   |
|                        |                          | US-  |                                      |  |   |
|                        |                          | US-  |                                      |  |   |
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**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication<br>Date/Filing Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns,<br>Lines, Where<br>Relevant Passages or<br>Relevant Figures<br>Appear | T <sup>6</sup> |
|-----------------------|--------------------------|---|---|---|---|----------------|
|                       |                          | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |   |   |   |                |
|                       | AE                       | EP 0914819  | 05-12-1999                                    | Fuisz Technologies                                    |   |                |
|                       | AF                       | GB 2202445  | 09-28-1988                                    | Melville  |   |                |
|                       |                          |   |   |   |   |                |
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Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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|  |   |                          |                            |
|--|---|--------------------------|----------------------------|
| Substitute for form 1449B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   | <b>Complete if Known</b> |                            |
|  |   | Application Number       | 10/748,999                 |
|  |   | Filing Date              | December 29, 2003          |
|  |   | First Named Inventor     | Rozalina Dimitrova         |
|  |   | Art Unit                 | 3767                       |
|  |   | Examiner Name            | Benjamin Huh               |
| Sheet  | 2 | of                       | 2                          |
|  |   | Attorney Docket Number   | ALLE0063-100 (17638 (BOT)) |

| NON PATENT LITERATURE DOCUMENTS |                          |   |                |
|---------------------------------|--------------------------|---|----------------|
| Examiner<br>Initials *          | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 | AG                       | Boyd et al., "The insulin secreting B-cell line, HIT-15, contains SNAP-25 which is a target for botulinum neurotoxin-A," <i>Mov Disorders</i> (1995) 10(3):376.   |                |
|                                 | AH                       | Ferrari et al., "The protein disulphide-isomerase family: unraveling a string of folds," <i>Biochem J</i> (1999) 339:1-10.  |                |
|                                 | AI                       | Habermann "125I-labeled neurotoxin from Clostridium botulinum A: preparation, binding to synaptosomes and ascent to the spinal cord," <i>Nauny-Schmiedeberg's Arch Pharmacol</i> (1974) 281:47-56.  |                |
|                                 | AJ                       | Marjama-Lyons et al., "Tremor-predominant Parkinson's Disease," <i>Drugs &amp; Aging</i> (2000) 4:273-278.  |                |
|                                 | AK                       | Naumann et al., "Botulinum toxin type A in the treatment of focal hyperhidrosis," <i>J Cutaneous Laser Therapy</i> (2001) 3(1):42-43.   |                |
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|-----------------------|--------------------|
| Examiner<br>Signature | Date<br>Considered |
|-----------------------|--------------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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